

**EPA PETITION FILE NUMBER 9E7662**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

MAR 09 2011

Dr. Michael Braverman  
Agent for Arizona Cotton Research and Protection Council  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Re: Arizona Cotton Research and Protection Council; *Aspergillus flavus* AF36  
EPA Registration No. 71693-1  
Amendment to add corn uses to the label  
Submissions dated 11/30/2009 and 12/15/2010  
Decision No. 424829

Dear Dr. Braverman:

The amendment referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that, within 15 days of the date of this letter, you submit a revised label to EPA, incorporating the changes listed below:

1. For the corn sublabel, add a restriction that the product is "FOR USE ONLY IN THE STATES OF TEXAS AND ARIZONA."
2. For the corn sublabel, add the EPA Registration Number, 71693-1.

If you have any questions regarding this letter, please contact Ms. Jeannine Kausch by telephone (703-347-8920) or email ([kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov)).

A stamped copy of the label is enclosed for your records.

Sincerely,

Keith A. Matthews, Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (1):

-*Aspergillus flavus* AF36 Accepted Label



# ***Aspergillus flavus* AF36**

## **MASTER LABEL**

**Sublabel A: Cotton**

**Sublabel B: Corn**

**Active Ingredient:**

<i>Aspergillus flavus</i> strain AF36*	0.0008%
Other Ingredients	99.9992%
Total	100.0000%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

**KEEP OUT OF REACH OF CHILDREN**

## **CAUTION**

**EPA Registration No. 71693-1**

**EPA Est. No. 71693-AZ-001**

**Arizona Cotton Research and Protection Council  
Phoenix, AZ 85040**

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated  
MAR 09 2011**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act  
as amended, for the pesticide  
registered under EPA Reg. No.  
71693-1**

# Aspergillus flavus AF36

FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS  
AND CALIFORNIA (Imperial, Riverside and San Bernadino counties only)

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally on the cotton crop. When applied to cotton just prior to first bloom, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693-1  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**  
Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other

waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated cotton fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

#### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to cotton to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed, which serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the seed will be covered with green spores. The fungus growing out will appear first as a white fuzz and then as a green fuzz. These green spores will then be spread to the crop by wind and insects in the same manner that the aflatoxin producing fungi are spread.

#### Ground Application:

1. Apply *Aspergillus flavus* AF36 with a cultivator mounted granular applicator to the surface of the soil under the plant canopy. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied in late May or early June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within three days after application of *Aspergillus flavus* AF36 will provide the best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application may diminish efficacy.

### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers:** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS



Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. **DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.**
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

**DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.**

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2010-0101; FRL-8368-7]**

***Aspergillus flavus* AF36; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the microbial pesticide, *Aspergillus flavus* AF36, in or on corn food and feed commodities, when applied/used as an antifungal agent. The Arizona Cotton Research and Protection Council submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an amendment to the existing exemption from the requirement of a tolerance for *Aspergillus flavus* AF36. This regulation eliminates the need to establish a maximum permissible level for residues of *Aspergillus flavus* AF36 under the FFDCA.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0101. All documents in the docket are listed in the

docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Shanaz Bacchus, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8097; e-mail address: [bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

###### ***A. Does this Action Apply to Me?***

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0101 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any



CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0101, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## **II. Background and Statutory Findings**

In the *Federal Register* of March 3, 2010 (75 FR 9596) (FRL-8811-2), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9E7662) by the Arizona Cotton Research and Protection Council, 3721 East Wier Ave., Phoenix, AZ 85040-2933. The petition requested that 40 CFR 180.1206 be amended by establishing an exemption from the requirement of a tolerance for residues of *Aspergillus flavus* AF36 in or on corn food and feed commodities. This notice referenced a summary of the petition prepared on behalf of the petitioner, Arizona Cotton Research and Protection Council, which is

available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, section 408(b)(2)(D) of FFDCA requires that EPA consider "available information concerning the cumulative effects of [a particular pesticide's] residues and other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The nature and toxicological profile of *Aspergillus flavus* AF36 was previously described in the **Federal Register** of July 14, 2003 (68 FR 41541) (FRL-7311-6). Those health effects data were the basis for establishing the tolerance exemption for *Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *Aspergillus flavus*, in or on cotton and its food/feed commodities in 40 CFR 180.1206 and also for temporary tolerance exemptions for experimental use of *Aspergillus flavus* AF36 on pistachio (72 FR 28871, May 23, 2007) (FRL-8129-4) and on corn (72 FR 72965, Dec. 26, 2007) (FRL-8342-1). EPA has reviewed the available data in support of this action.

*Aspergillus flavus* AF36 is neither toxic nor infective via the oral and pulmonary routes. It was placed in Toxicity Category IV for acute oral effects. The Toxicity Category III designation for acute inhalation effects is based on the granular nature of the pesticide and the submitted pulmonary studies. This microbial pesticide has been used for more than a decade in experimental laboratory and field trials and in agricultural practice on cotton in Arizona, California, and Texas without any reports of adverse dermal irritation or hypersensitivity effects. Data and information from the public literature indicate that there will not be any incremental harm from the use of *Aspergillus flavus* AF36 for reduction of aflatoxin. No further toxicological data are

required to support this exemption from the requirement of a tolerance for *Aspergillus flavus* AF36 in or on the food and feed commodities of corn.

#### IV. Aggregate Exposure

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### A. Dietary Exposure

1. *Food.* Current uses of *Aspergillus flavus* AF36 include use on cotton, pistachios, and corn. EPA does not expect these uses to result in any exposure that is greater than background levels of *Aspergillus flavus*. As a microbial pesticide for use on corn, *Aspergillus flavus* AF36 is labeled for application from the V7 growth stage (i.e., approximately 21–25 days after plant emergence) until silking (i.e., approximately 55–66 days after plant emergence). Once applied to corn and after exposure to moisture, *Aspergillus flavus* AF36 germinates, using the carrier upon which it is placed as a nutrient source, and effectively displaces aflatoxin-producing strains of *Aspergillus flavus* without increasing levels of cyclopiazonic acid (Ref. 1). Further, multiple-year studies, which monitored air and soil populations of *Aspergillus flavus*, including strain AF36, in cotton fields, demonstrated replacement of toxigenic (aflatoxin-producing) fungi with atoxic fungi without an increase in the overall quantity of *Aspergillus flavus* beyond normal background levels (Refs. 2 and 3). Although residues from the use of pesticides containing *Aspergillus flavus* AF36 will likely be present on corn at the time of harvest

(although likely not at higher levels than background), much like other microbial pest control agents, commodity-processing procedures (e.g., peeling, shucking, washing, and cooking) should further reduce levels of *Aspergillus flavus* AF36 below typical background levels (Ref. 4). Finally, even with the potential for negligible exposure to *Aspergillus flavus* AF36 on edible corn commodities, a previously reviewed and described acute oral toxicity and pathogenicity study (see Unit III. of the **Federal Register** of July 14, 2003 (68 FR 41541) (FRL-7311-6)) showed no toxicity or infectivity in animals exposed to high levels of this active ingredient.

2. *Drinking water exposure.* Exposure to *Aspergillus flavus* AF36 via drinking water from all uses of *Aspergillus flavus* AF36 is not likely to be greater than current/existing exposures to *Aspergillus flavus* strains, which are already present in the environment. Potential risks via exposure to drinking water or runoff may be mitigated by, among other things, percolation through soil. Thus, EPA expects exposure via drinking water from the proposed use of this non-aflatoxin-producing strain of *Aspergillus flavus* to be low, or at least not greater than existing background levels. In any event, any drinking water exposure is not likely to pose any incremental risk to adult humans, infants and children because of the lack of toxicity or infectivity of this substance. In fact, displacement of the toxigenic strains of *Aspergillus flavus* by AF36 may decrease exposure and risk to the toxigenic strains of *Aspergillus flavus* in the environment.

#### *B. Other Non-Occupational Exposure*

Dermal and inhalation non-occupational exposure are expected to be minimal to non-existent for the proposed use of *Aspergillus flavus* AF36 in or on corn.

*Aspergillus flavus* AF36 is to be applied to agricultural sites not in the proximity of residential areas, schools, nursing homes, or daycares. Additionally, the *Aspergillus flavus* AF36 product to be applied to corn is in a granular form, thereby minimizing spray drift even for application methods (e.g., aerial) that may be more likely to result in pesticide movement offsite.

#### **V. Cumulative Effects from Substances with a Common Mechanism of Toxicity**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] residues and other substances that have a common mechanism of toxicity.”

EPA has not found *Aspergillus flavus* AF36 to share a common mechanism of toxicity with any other substances, and *Aspergillus flavus* AF36 does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that *Aspergillus flavus* AF36 does not have a common mechanism of toxicity with other substances. Following from this, therefore, EPA concludes that there are no cumulative effects associated with *Aspergillus flavus* AF36 that need to be considered. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

#### **VI. Determination of Safety for U.S. Population, Infants and Children**

There is reasonable certainty that no harm will result from aggregate exposures to residues of *Aspergillus flavus* AF36, in its use as an antifungal agent, to the U. S.



population, including infants and children. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed previously, there appears to be no potential for harm from this fungus in its use as an antifungal agent via dietary exposure since the organism is non-toxic and non-pathogenic to animals and humans. EPA has arrived at this conclusion based on the very low levels of mammalian toxicity for acute oral and pulmonary effects with no toxicity or infectivity at the doses tested (See Unit III. above).

FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, EPA concludes that the fungus, *Aspergillus flavus* AF36, is non-toxic to mammals, including infants and children. Because there are no threshold effects of concern to infants, children and adults when *Aspergillus flavus* AF36 is used as labeled, the provision requiring an additional margin of safety does not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *Aspergillus flavus* AF36.

## VII. Other Considerations

### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Aspergillus flavus* AF36.

### *C. Response to Comments*

In total, four comments were received in response to the **Federal Register** notice published by EPA to announce receipt of the Arizona Cotton Research and Protection Council's petition. Three comments expressed support for the petition, while the other comment was filed in opposition.

The one substantive, negative comment indicated overall support for *Aspergillus flavus* NRRL 21882, another microbial pesticide intended for aflatoxin reduction. Primarily, this commenter articulated concern about the possible expression of cyclopiazonic acid (CPA) by the *Aspergillus flavus* 36 atoxigenic strain. That is, the commenter asserted that, while reduction of aflatoxin is an admirable goal, the substitution of one mycotoxin, aflatoxin, for another, CPA (albeit a less toxic one), was



not acceptable. The commenter claimed that CPA could only be observed in field trials and was not directly observed by analysis of the active ingredient.

Field trial data presented by the petitioner to EPA demonstrated that there was no increase in CPA levels above background in treated corn. In addition, the use of *Aspergillus flavus* AF36 reduced aflatoxin levels in the treated fields compared to untreated plots. Given this new information (See Ref. 1), as well as previously reviewed data on *Aspergillus flavus* AF36, EPA has concluded there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* AF36 in or on the food and feed commodities of corn, when applied/used as an antifungal agent. Thus, under the standard in FFDCA section 408(c)(2), a tolerance exemption is appropriate.

#### VIII. Conclusions

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Aspergillus flavus* AF36. Therefore, an exemption is established for residues of *Aspergillus flavus* AF36 in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover, when applied/used as an antifungal agent.

#### IX. References

1. U.S. EPA. 2011. *Aspergillus flavus* AF36 Use on Corn. Memorandum from J.V. Gagliardi, Ph.D. and J.L. Kough, Ph.D. to S. Bacchus dated February 24, 2011

(available as "Supporting & Related Materials" within docket ID number EPA-HQ-OPP-2010-0101 at <http://www.regulations.gov>).

2. U.S. EPA. 2003. Environmental Hazard Assessment for the Microbial Pesticide, *Aspergillus flavus* AF36 for Conditional Registration in Arizona and EUP Extension in Texas. Memorandum from G.S. Tomimatsu, Ph.D. and Z. Vaituzis, Ph.D. to S. Bacchus dated May 16, 2003.

3. U.S. EPA. 2003. BPPD Review of Soil and Air Monitoring Studies and Product Performance Testing (Efficacy) Submitted by USDA Southern Regional Research Center/IR-4 as a Condition of Registration and EUP Extension (Texas) for *Aspergillus flavus* AF36. Memorandum from G.S. Tomimatsu, Ph.D. and J. Kough, Ph.D. to S. Bacchus dated May 15, 2003.

4. U.S. EPA. 1996. Microbial Pesticide Test Guidelines – Background for Residue Analysis of Microbial Pest Control Agents (OPPTS 885.2000). Available from: [http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series885.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm).

#### **X. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the requirement~~s~~ of a tolerance under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled *Protection of*

✓

*Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### **XI. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 09, 2011

A handwritten signature in black ink, appearing to read "J. A. Smith", is written over a horizontal line.

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1206, paragraph (c) is revised to read as follows:

**§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.**

\* \* \* \* \*

(c) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36 in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover, when applied/used as an antifungal agent.



NATIONAL  
CORN GROWERS  
ASSOCIATION

February 22, 2011

Dr. Steven Bradbury  
Director, Office of Pesticide Programs  
U.S. Environmental Protection Agency  
2777 S. Crystal Drive  
Arlington, VA 22202-3553

Dr. Bradbury:

For a number of years, the National Corn Growers Association has taken a leading role in the effort to mitigate the presence and impact of aflatoxin in corn. It remains a critical issue for many of our growers, particularly in the south, who often face aflatoxin pressure.


Since 2006, the Texas Corn Producers Board has funded research conducted by Dr. Peter Cotty at the University of Arizona to evaluate the efficacy of a particular biopesticide, AF 36, on corn in Texas. This was done under an Experimental Use Permit (EUP) issued by your Agency. Under the EUP, we have had three years of direct applications of AF 36 to corn acres in Texas, and the product shows real promise. In certain field trials, AF 36 reduced the presence of aflatoxin to less than 20 parts per billion while other nearby untreated fields were often in excess of 300 parts per billion.

While the EUP expired on December 31, 2010, we know that the Agency received a Section 3 application for AF 36 on December 20 and that the product was assigned to a reviewer in the Biopesticides and Pollution Prevention Division. Under the Pesticide Registration Improvement Act, we understand the negotiated deadline for a registration decision currently stands at August 17, 2011.

We are requesting that EPA expedite the review of this important product. If a Section 3 registration is not approved in time to allow for distribution in preparation for the Texas growing season, we face losing important continuity that we have been able to achieve on corn acres in Texas over the past few years. If possible, we urge EPA to issue a registration prior to April 1.

NCGA has rarely, if ever, requested an expedited review of a product registration; however, this is a unique circumstance due to the lack of tools available to combat the aflatoxin problem. Please let us know if we can be of assistance or if any additional information from the grower community might be helpful.

Regards,

  
Barton Schott  
President

**WWW.NCGA.COM**

**NATIONAL OFFICE**  
632 Cepi Dr.  
Chesterfield, MO 63005  
(636) 733-9004  
Fax: (636) 733-9005

**WASHINGTON, DC OFFICE**  
122 C Street NW, Suite 510  
Washington, DC 20001-2109  
(202) 628-7001  
Fax: (202) 628-1933



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

Re: *Aspergillus flavus* AF36 - (EPA Reg. No. 71693-1)  
Proposed New Use on Corn - Data Deficiencies - MRID 47935101  
Product Performance Test Guidelines (OPPTS 810.1000)  
Amend Established Tolerance Exemption  
OPP Decision Numbers:  
D-424829 - EPA Reg. No. 71693-1  
D-424831 - Pesticide Petition: 9E7662 - *Aspergillus flavus* AF36  
Application Dated: November 11, 2009 and December 01, 2009, respectively.  
EPA Receipt Dates: December 15, 2009, for both applications

Dear Dr. Braverman:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD) and deficiencies have been identified in the *Aspergillus flavus* AF36 efficacy study on corn (MRID 47935101).

On September 23, 2010, BPPD met with you and provided a copy of its review (dated August 26, 2010) of the product performance (efficacy) data submitted for *Aspergillus flavus* AF36 on corn (MRID 47935101). Data are required from the studies conducted with *A. flavus* AF36 from an Experimental Use Permit (EUP; EPA Reg. No. 71693-EUP-2) in 2009 and 2010 from both Texas and Arizona to demonstrate the efficacy of *Aspergillus flavus* AF36 on corn. The report must include planting dates, AF36 treatment dates, stage of corn at treatment, conditions at and shortly after, treatment (i.e. irrigation or rain events), acres represented by each sample, number of samples per plot, type(s) of corn planted, distance(s) between plots, harvest dates, percent AF36 with aflatoxin and cyclopiazonic acid levels for each sample. Your response should include a discussion concerning whether areas located near the treated and untreated plots were treated with atoxigenic *Aspergillus flavus* AF36 or *Aspergillus flavus* NRRL 21882 (AflaGuard) previously for any testing and/or commercial purposes.

At the September 23, 2010 meeting, we also asked you consider whether an extension of the EUP might be needed, since it expires January 4, 2011; the associated temporary tolerance exemption for *Aspergillus flavus* AF36 on corn does not expire until December 30, 2011.



The referenced application as submitted under the Pesticide Registration improvement Act (PRIA) guaranteed a regulatory decision for the action category (B631) of 9 months. By regulation, the Agency is obligated to give you 75 days (40 CFR §152.105) in which to address the deficiencies identified above. However, there is not enough time remaining for you to submit the information and for BPPD to complete the review by the PRIA decision due date of November 13, 2010.

Therefore, you may renegotiate the PRIA due date or withdraw the application and resubmit it when you have all the information. Should you choose not to renegotiate the PRIA decision due date, or withdraw the application, the Agency will issue a letter stating that it cannot grant the application under PRIA on or about November 13, 2010. Please be advised that the resubmission of a withdrawn application will be considered a new application, and will be subject to a new registration decision time under PRIA. In the event the application is not granted, you will still have the remaining time (75 days from the date of this letter) in which to submit the required information. The Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Shanaz Bacchus on or before October 30, 2010, by phone (703-308-8097) or by e-mail ([bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)) with your response to this letter.

Sincerely,



Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

Re: *Aspergillus flavus* AF36 - (EPA Reg. No. 71693-1)  
Proposed New Use on Corn - Data Deficiencies - MRID 47935101  
Product Performance Test Guidelines (OPPTS 810.1000)  
Amend Established Tolerance Exemption  
OPP Decision Numbers:  
D-424829 - EPA Reg. No. 71693-1  
D-424831 - Pesticide Petition: 9E7662 - *Aspergillus flavus* AF36  
Application Dated: November 11, 2009 and December 01, 2009, respectively.  
EPA Receipt Dates: December 15, 2009, for both applications

Dear Dr. Braverman:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD) and deficiencies have been identified in the *Aspergillus flavus* AF36 efficacy study on corn (MRID 47935101).

On September 23, 2010, BPPD met with you and provided a copy of its review (dated August 26, 2010) of the product performance (efficacy) data submitted for *Aspergillus flavus* AF36 on corn (MRID 47935101). Data are required from the studies conducted with *A. flavus* AF36 from an Experimental Use Permit (EUP; EPA Reg. No. 71693-EUP-2) in 2009 and 2010 from both Texas and Arizona to demonstrate the efficacy of *Aspergillus flavus* AF36 on corn. The report must include planting dates, AF36 treatment dates, stage of corn at treatment, conditions at and shortly after, treatment (i.e. irrigation or rain events), acres represented by each sample, number of samples per plot, type(s) of corn planted, distance(s) between plots, harvest dates, percent AF36 with aflatoxin and cyclopiazonic acid levels for each sample. Your response should include a discussion concerning whether areas located near the treated and untreated plots were treated with atoxigenic *Aspergillus flavus* AF36 or *Aspergillus flavus* NRRL 21882 (AflaGuard) previously for any testing and/or commercial purposes.

At the September 23, 2010 meeting, we also asked you consider whether an extension of the EUP might be needed, since it expires January 4, 2011; the associated temporary tolerance exemption for *Aspergillus flavus* AF36 on corn does not expire until December 30, 2011.

The referenced application as submitted under the Pesticide Registration improvement Act (PRIA) guaranteed a regulatory decision for the action category (B631) of 9 months. By regulation, the Agency is obligated to give you 75 days (40 CFR §152.105) in which to address the deficiencies identified above. However, there is not enough time remaining for you to submit the information and for BPPD to complete the review by the PRIA decision due date of November 13, 2010.

Therefore, you may renegotiate the PRIA due date or withdraw the application and resubmit it when you have all the information. Should you choose not to renegotiate the PRIA decision due date, or withdraw the application, the Agency will issue a letter stating that it cannot grant the application under PRIA on or about November 13, 2010. Please be advised that the resubmission of a withdrawn application will be considered a new application, and will be subject to a new registration decision time under PRIA. In the event the application is not granted, you will still have the remaining time (75 days from the date of this letter) in which to submit the required information. The Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Shanaz Bacchus on or before October 30, 2010, by phone (703-308-8097) or by e-mail ([bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)) with your response to this letter.

Sincerely,



Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)

# DATA PACKAGE BEAN SHEET

Date: 10-Jan-2011

Page 1 of 2

Decision #: 424829

DP #: (385616)

PRIA

Parent DP #:

Submission #: 887567

## \*\*\* Registration Information \*\*\*

Registration: 71693-1 - Aspergillus Flavus AF36

Company: 71693 - ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Risk Manager: RM 92 - Sheryl Reilly - (703) 308-8269 Room# PY1 S-8741

Risk Manager Reviewer: Shanaz Bacchus SBACCHUS

Sent Date: 20-Dec-2010

Calculated Due Date: 17-Aug-2011

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (B631) AMEND ESTABLISHED TOLERANCE EXEMPTION;

Ingredients: 006456, Aspergillus flavus 36 colonized wheat seed(.0008%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Jan-2011

Due Back: \_\_\_\_\_

DP Ingredient: 006456, Aspergillus flavus 36 colonized wheat seed

DP Title: efficacy cpa

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

### Date In

### Date Out

Organization: BPPD / MPB

10-Jan-2011

Last Possible Science Due Date: 20-Nov-2010

Team Name: MPB Health & Characterization

10-Jan-2011

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

10-Jan-2011

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

Can be printed on its own page

## \*\*\* Data Package Instructions \*\*\*

Attached for your review is an efficacy study of Aspergillus flavus AF36 on corn in response to the attached 75 day letter that was sent to the company on 10/06/10. Do these data support the request to establish a tolerance exemption for A. flavus AF36 on corn?

DP#: (385616)

\*\*\* Studies Sent for Review \*\*\*

Decision#: (424829)

MRID	MRID Status	Citation Reference	Guideline
48330101		Cotty, P.; Wakelyn, P.; Braverman, M. (2010) Product Performance Data: Efficacy of AF36 in Corn 2009 Commercial Field Tests: Amendment #1 to MRID 47935101. Project Number: 0378B. Unpublished study prepared by U.S. Dept. of Agriculture, Agr.Res. Serv., Wakelyn Associates, LLC and Interregional Research Project No. 4. 58 p.	93-16/Products for control of organisms producing mycotoxins



Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

483301-00

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
ir4.rutgers.edu

Shanaz Bacchus, Regulatory Action Leader  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

December 15, 2010

RE: Registration AF36 (Aspergillus flavus AF36) on Corn  
Company Number 71693-1 PP 9E7662 IR-4 PR# 0378B

Dear Shanaz

This submission is in response to a 75 day letter from Dr Sheryl Reilly dated October 6, 2010(attached)regarding the request for additional efficacy data for AF36 on corn. Data from 2008 was previously submitted (MRID 47935101)and this current submission includes 2009 data. Please find attached , Form 8570-1 Application for Pesticide for the use of an atoxigenic *Aspergillus flavus* AF36 to displace toxigenic *Aspergillus flavus* on corn. I have also attached 5 copies of the corn label for your review.

The two years of field data are consistent and the primary conclusions drawn from this research are as follows:

1. **AFLATOXIN:** In both 2008 and 2009, aflatoxin concentration in corn grain from fields treated with AF36 were less than in corn grain from fields not treated. Aflatoxin concentration decreased as incidence of AF36 increased (there was a significant inverse correlation)
2. **CYCLOPIAZONIC ACID:** In both 2008 and 2009, CPA concentration was not significantly different in corn grain from fields treated with AF36 than in corn grain from fields not treated. AF36 incidence was not significantly correlated with CPA concentration, but the overall trend was that as AF36 incidence increased, CPA concentration decreased.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.



**DATA ASSOCIATED WITH THIS SUBMISSION**

**48330101** Volume 1 of 1 Product Performance Data: Efficacy of AF36 in Corn 2009  
Commercial Field Tests. **Amendment #1 to MRID 47935101** Dec 13, 2010  
58 pages.

Sincerely,

A handwritten signature in cursive script, reading "Michael Braverman".

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540  
Tel (732) 932-9575 ext 4610  
Fax 609.514.2612



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

Re: *Aspergillus flavus* AF36 - (EPA Reg. No. 71693-1)  
Proposed New Use on Corn - Data Deficiencies - MRID 47935101  
Product Performance Test Guidelines (OPPTS 810.1000)  
Amend Established Tolerance Exemption  
OPP Decision Numbers:  
D-424829 - EPA Reg. No. 71693-1  
D-424831 - Pesticide Petition: 9E7662 - *Aspergillus flavus* AF36  
Application Dated: November 11, 2009 and December 01, 2009, respectively.  
EPA Receipt Dates: December 15, 2009, for both applications

Dear Dr. Braverman:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD) and deficiencies have been identified in the *Aspergillus flavus* AF36 efficacy study on corn (MRID 47935101).

On September 23, 2010, BPPD met with you and provided a copy of its review (dated August 26, 2010) of the product performance (efficacy) data submitted for *Aspergillus flavus* AF36 on corn (MRID 47935101). Data are required from the studies conducted with *A. flavus* AF36 from an Experimental Use Permit (EUP; EPA Reg. No. 71693-EUP-2) in 2009 and 2010 from both Texas and Arizona to demonstrate the efficacy of *Aspergillus flavus* AF36 on corn. The report must include planting dates, AF36 treatment dates, stage of corn at treatment, conditions at and shortly after, treatment (i.e. irrigation or rain events), acres represented by each sample, number of samples per plot, type(s) of corn planted, distance(s) between plots, harvest dates, percent AF36 with aflatoxin and cyclopiazonic acid levels for each sample. Your response should include a discussion concerning whether areas located near the treated and untreated plots were treated with atoxigenic *Aspergillus flavus* AF36 or *Aspergillus flavus* NRRL 21882 (AflaGuard) previously for any testing and/or commercial purposes.

At the September 23, 2010 meeting, we also asked you consider whether an extension of the EUP might be needed, since it expires January 4, 2011; the associated temporary tolerance exemption for *Aspergillus flavus* AF36 on corn does not expire until December 30, 2011.



The referenced application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed a regulatory decision for the action category (B631) of 9 months. By regulation, the Agency is obligated to give you 75 days (40 CFR §152.105) in which to address the deficiencies identified above. However, there is not enough time remaining for you to submit the information and for BPPD to complete the review by the PRIA decision due date of November 13, 2010.

Therefore, you may renegotiate the PRIA due date or withdraw the application and resubmit it when you have all the information. Should you choose not to renegotiate the PRIA decision due date, or withdraw the application, the Agency will issue a letter stating that it cannot grant the application under PRIA on or about November 13, 2010. Please be advised that the resubmission of a withdrawn application will be considered a new application, and will be subject to a new registration decision time under PRIA. In the event the application is not granted, you will still have the remaining time (75 days from the date of this letter) in which to submit the required information. The Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Shanaz Bacchus on or before October 30, 2010, by phone (703-308-8097) or by e-mail ([bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)) with your response to this letter.

Sincerely,



Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

**Aspergillus flavus AF36** is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, **Aspergillus flavus AF36** competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
<b>IF SWALLOWED:</b>	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
<b>IF INHALED:</b>	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>IF IN EYES:</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

#### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# DATA PACKAGE BEAN SHEET

Date: 10-Feb-2011

Page 1 of 1

Decision #: 424831

DP #: (386710)

PRIA

Parent DP #:

Submission #: 864140

## \*\*\* Registration Information \*\*\*

Registration: 9E7662 -

Company: 71693 - ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Risk Manager: RM 92 - Sheryl Reilly - (703) 308-8269 Room# PY1 S-8741

Risk Manager Reviewer: Shanaz Bacchus SBACCHUS

Sent Date: 15-Dec-2009

Calculated Due Date: 17-Aug-2011

Edited Due Date: \_\_\_\_\_

Type of Registration: Tolerance Petition

Action Desc: (B631.0) AMEND ESTABLISHED TOLERANCE EXEMPTION;

Ingredients: 006456, Aspergillus flavus 36 colonized wheat seed

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Feb-2011

Due Back: \_\_\_\_\_

DP Ingredient: 006456, Aspergillus flavus 36 colonized wheat seed

DP Title: AF36 use on corn - PP 9E7662

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

#### Date In

#### Date Out

Organization: BPPD / MPB

10-Feb-2011

Last Possible Science Due Date: 20-Nov-2010

Team Name: MPB Health & Characterization

10-Feb-2011

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

10-Feb-2011

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review Volumes 1 and 2 for use of Aspergillus flavus AF36 on corn - the petitioner is requesting an exemption from tolerance. The formulation (CSF attached) is 71693-1 that is registered for use on cotton. A bean for review of the efficacy data was provided earlier under 71693-1

# DATA PACKAGE BEAN SHEET

Date: 10-Feb-2011

Page 1 of 1

Decision #: 424831

DP #: (386710)

PRIA

Parent DP #:

Submission #: 864140

## \*\*\* Registration Information \*\*\*

Registration: 9E7662 -

Company: 71693 - ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

Risk Manager: RM 92 - Sheryl Reilly - (703) 308-8269 Room# PY1 S-8741

Risk Manager Reviewer: Shanaz Bacchus SBACCHUS

Sent Date: 15-Dec-2009

Calculated Due Date: 17-Aug-2011

Edited Due Date: \_\_\_\_\_

Type of Registration: Tolerance Petition

Action Desc: (B631.0) AMEND ESTABLISHED TOLERANCE EXEMPTION;

Ingredients: 006456, Aspergillus flavus 36 colonized wheat seed

CORN

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Feb-2011

Due Back: \_\_\_\_\_

DP Ingredient: 006456, Aspergillus flavus 36 colonized wheat seed

DP Title: AF36 use on corn - PP 9E7662

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

### Date In

### Date Out

Organization: BPPD / MPB

10-Feb-2011

Last Possible Science Due Date: 20-Nov-2010

Team Name: MPB Health & Characterization

10-Feb-2011

Science Due Date: \_\_\_\_\_

Reviewer Name: Gagliardi, Joel

10-Feb-2011

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Please review Volumes 1 and 2 for use of Aspergillus flavus AF36 on corn - the petitioner is requesting an exemption from tolerance. The formulation (CSF attached) is 71693-1 that is registered for use on cotton. A bean for review of the efficacy data was provided earlier under 71693-1

VOLUME 1 OF 3

PP 9E7662  
Corn

Study Title

Tolerance Petition- Establishment of an Exemption from tolerance  
for *Aspergillus flavus* –AF36 in or on Corn

Author

Michael Braverman, Ph.D.  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540

Submitted by

Michael Braverman, Ph.D.  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540

Study Completed On

November 25, 2009

Laboratory Project ID Number

IR-4 PR No. 0378B

Page 1 of 19

Petition for Exemption from Tolerance  
**Aspergillus flavus- AF36**

**TABLE OF CONTENTS**

<b>Tab #</b>	<b>Section: description</b>
<b>A</b>	Section A: Name, chemical identity, and composition
<b>B</b>	Section B: Amount, frequency, and time of application of the pesticide chemical
<b>C</b>	Section C: Investigations made with respect to the safety of the active ingredient
<b>D</b>	Section D: Tests on the amount of residue remaining
<b>E</b>	Section E: Practicable methods for removing residue that exceeds any proposed tolerance
<b>F</b>	Section F: Proposed tolerances
<b>G</b>	Section G: Reasonable grounds in support of the petition





Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
ir4.rutgers.edu

Shanaz Bacchus, Regulatory Action Leader  
Biopesticides and Pollution Prevention Division  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

December 1, 2009

Subject: *Aspergillus flavus* AF36 Section 3 Registration  
Company number 71693

Dear Shanaz

Enclosed, please find an Application for Pesticide for the above subject product. Enclosed also are: The Method of Support for Product chemistry, toxicology and ecological data; confidential statement of formula ; proposed label (5 copies) and most importantly-product performance data .

In support of this application, please refer to the petition *Aspergillus flavus* Tolerance Exemption for Corn.

This registration is being submitted by IR-4 on behalf of the Arizona Cotton Research and Protection Council.

As per PR Notice 88-4, the registration of the above use is exempt from fees.

Sincerely,

Michael Braverman  
Manager, Biopesticide Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08549  
(732) 932-9575 ext 4610

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

**RUTGERS**  
THE STATE UNIVERSITY  
OF NEW JERSEY

V2 of 3

PP 9 E 7662

Corn



## ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

3721 East Wier Avenue  
Phoenix, Arizona 85040-2933  
(602) 438-0059 - Phone  
(602) 438-0407 - Fax

Shanaz Bacchus, Regulatory Action Leader  
c/o Document Processing Desk  
Office of Pesticide Programs (7504P)  
Biopesticides & Pollution Prevention Division (BPPD)  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501  
(703)308-8097

November 30, 2009

RE: Registration AF36 (*Aspergillus flavus* AF36) on Corn  
Company Number 71693

Dear Shanaz

Please find attached , a Notice of Filing and Form 8570-1 Application for Pesticide for the use of an atoxigenic *Aspergillus flavus* AF36 to displace toxigenic *Aspergillus flavus* on corn. Waivers for health effects and non -target /environmental effects are cited in the Administrative volume as the citations of MRID numbers from previous submissions. Please refer to the petition cover letter for a listing of supporting volumes.

This letter also authorizes EPA to review all pertinent data for *Aspergillus flavus* AF36 previously submitted to EPA in conjunction with this petition.



Sincerely,

Larry Antilla  
Sponsor and Submitter  
Staff Director  
Arizona Cotton Research and Protection Council



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

		United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input checked="" type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>					
1. Company/Product Number 71693		2. EPA Product Manager Shanaz Bacchus		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Aspergillus flavus AF36		PM# 703-308-8097			
5. Name and Address of Applicant (Include ZIP Code) Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933  <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____			
<b>Section - II</b>					
<input checked="" type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.			
<b>Explanation:</b> Use additional page(s) if necessary. (For section I and Section II.)  There is a current Section 3 registration for AF36 on cotton and an Experimental Use Permit on Corn. This is a label amendment to add corn to the label as part of a Section 3 registration for corn and to amend the tolerance by establishing a tolerance exemption for AF36 on corn.					
<b>Section - III</b>					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Bulk boxes, bags		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1.8g	No. per container 1	If "Yes" Package wgt. 1	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Plastic bag, bulk box 50,1000, 3000 lb		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____					
<b>Section - IV</b>					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Michael Braverman, Ph.D.		Title Biopesticide Manager, IR-4		Telephone No. (Include Area Code) 732-932-9575ext. 161C	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamp)
2. Signature 		3. Title Staff Director			
4. Typed Name Larry Antilla		5. Date 11-30-09			

Volume 2 of 3

Registration Volume- Administrative Materials

*Aspergillus flavus* AF36 Corn

Michael Braverman, Ph.D.  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08549

December 7, 2009

Project ID Number

IR-4 PR No. 0378B

Page 1 of 20

Registration Volume  
Aspergillus flavus AF-36 Corn

<u>TABLE OF CONTENTS</u>	<u>REFERENCE NUMBER</u>
LETTER OF TRANSMITTAL .....	COVER
LETTER OF AUTHORIZATION.....	Reference 1
CONFIDENTIAL STATEMENT OF FORMULA .....	Reference 2
PRODUCT CHEMISTRY DATA .....	Reference 3
PROPOSED LABEL (5 COPIES).....	Reference 4
TOXICOLOGY DATA .....	Reference 5
ECOLOGICAL EFFECTS DATA .....	Reference 6
PRODUCT PERFORMANCE DATA .....	Reference 7

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

#### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OCT 06 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Michael Braverman, Ph.D.  
Manager, Biopesticide and Organic Support Program  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, NJ 08540

Re: *Aspergillus flavus* AF36 - (EPA Reg. No. 71693-1)  
Proposed New Use on Corn - Data Deficiencies - MRID 47935101  
Product Performance Test Guidelines (OPPTS 810.1000)  
Amend Established Tolerance Exemption  
OPP Decision Numbers:  
D-424829 - EPA Reg. No. 71693-1  
D-424831 - Pesticide Petition: 9E7662 - *Aspergillus flavus* AF36  
Application Dated: November 11, 2009 and December 01, 2009, respectively.  
EPA Receipt Dates: December 15, 2009, for both applications

Dear Dr. Braverman:

The applications referred to above, submitted in connection with registration under FIFRA section 3(c)(5) have been reviewed by the Biopesticides and Pollution Prevention Division (BPPD) and deficiencies have been identified in the *Aspergillus flavus* AF36 efficacy study on corn (MRID 47935101).

On September 23, 2010, BPPD met with you and provided a copy of its review (dated August 26, 2010) of the product performance (efficacy) data submitted for *Aspergillus flavus* AF36 on corn (MRID 47935101). Data are required from the studies conducted with *A. flavus* AF36 from an Experimental Use Permit (EUP; EPA Reg. No. 71693-EUP-2) in 2009 and 2010 from both Texas and Arizona to demonstrate the efficacy of *Aspergillus flavus* AF36 on corn. The report must include planting dates, AF36 treatment dates, stage of corn at treatment, conditions at and shortly after, treatment (i.e. irrigation or rain events), acres represented by each sample, number of samples per plot, type(s) of corn planted, distance(s) between plots, harvest dates, percent AF36 with aflatoxin and cyclopiazonic acid levels for each sample. Your response should include a discussion concerning whether areas located near the treated and untreated plots were treated with atoxigenic *Aspergillus flavus* AF36 or *Aspergillus flavus* NRRL 21882 (AflaGuard) previously for any testing and/or commercial purposes.

At the September 23, 2010 meeting, we also asked you consider whether an extension of the EUP might be needed, since it expires January 4, 2011; the associated temporary tolerance exemption for *Aspergillus flavus* AF36 on corn does not expire until December 30, 2011.

The referenced application as submitted under the Pesticide Registration improvement Act (PRIA) guaranteed a regulatory decision for the action category (B631) of 9 months. By regulation, the Agency is obligated to give you 75 days (40 CFR §152.105) in which to address the deficiencies identified above. However, there is not enough time remaining for you to submit the information and for BPPD to complete the review by the PRIA decision due date of November 13, 2010.

Therefore, you may renegotiate the PRIA due date or withdraw the application and resubmit it when you have all the information. Should you choose not to renegotiate the PRIA decision due date, or withdraw the application, the Agency will issue a letter stating that it cannot grant the application under PRIA on or about November 13, 2010. Please be advised that the resubmission of a withdrawn application will be considered a new application, and will be subject to a new registration decision time under PRIA. In the event the application is not granted, you will still have the remaining time (75 days from the date of this letter) in which to submit the required information. The Agency will continue to work on your application, but it will not be subject to the PRIA time frame. Please contact Shanaz Bacchus on or before October 30, 2010, by phone (703-308-8097) or by e-mail ([bacchus.shanaz@epa.gov](mailto:bacchus.shanaz@epa.gov)) with your response to this letter.

Sincerely,



Sheryl K. Reilly, Ph.D.  
Chief, Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)

# *Aspergillus flavus* AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
<b>IF SWALLOWED:</b>	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
<b>IF INHALED:</b>	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>IF IN EYES:</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

#### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

#### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

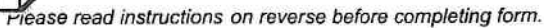
**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.



# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

**Aspergillus flavus AF36** is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, **Aspergillus flavus AF36** competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

#### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

#### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**Returnable/Refillable Bulk Containers-** Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 12-14-09

Experts In-Processing Signature: M F HARRINGTON Date 12-18-09 Fee Paid: Yes     

Division management contacted on issues No      Yes      Date     

EPA Reg. Number: <u>9E7662</u>		EPA Receipt Date: <u>12-14-09</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type					X
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)			yes	no	
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)			yes	no	
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)					X
	a) Selective Method (Fee category experts use)			yes	no	
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )	X		
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

\* The label and notice of tolerance petition filing are the only documents present.  
\* Data associated with submission is consistent with FR notice 06-5

MRID 479351

\* N/A – Not Applicable

IK

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

December 18, 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-424831  
EPA File Symbol or Registration Number: 9E7662  
Product Name: Aspergillus Flavus AF36 / Corn  
EPA Receipt Date: 14-Dec-2009  
EPA Company Number: 71693  
Company Name: ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL

CHARLENE R. NEAL  
ARIZONA COTTON RESEARCH AND PROTECTION COUNCIL  
3721 EAST WIER AVENUE  
PHOENIX, AZ 85040-2933

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B631.0

AMEND ESTABLISHED TOLERANCE EXEMPTION;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,  
Front End Processing Staff  
Information Technology & Resources Management Division

A handwritten signature in black ink, appearing to read "John Smith", written over the typed name and title.



## Fee for Service

{864140s~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 92

Receipt No.

S- 864140

EPA File Symbol/Reg. No.

9E7662

Pin-Punch Date:

12/15/2009

☐ This item is NOT subject to FFS action.

### Action Code:

Requested: B631

Granted: B631

Amount Due: \$ 11,025\*

\*applicant is claiming 100% IR-4 fee exemption

### Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Alan Reynolds Date: 12/17/09

Remarks:

Note - This is tied to a concurrent action  
(71693-1; S-864107)

# Receipt for Tolerance Petition

S: 864140

Resubmission: ☐ Yes ☒ No

Regulatory Type: Tolerance Petition

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 71693 ARIZONA COTTON RESEARCH AND PROTECTIO



Risk Mgr: Biologicals & Pollution Prevention Division, PM Team 92

Petition #: 9E7662

Fee Waived: ☐ Yes ☒ No

Fee:

Petition Type: E - Minor Use (IR-4/State)

Print Letter

Enter More Information

Tracking

Application Date: 01-Dec-2009



OPP Rec'd Date: 14-Dec-2009



Front End Date: 15-Dec-2009



Risk Manager Send Date: 15-Dec-2009



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

exemption from tolerance for Aspergillus flavus AF36/corn

New Ingredient:

Request Date:

New Ingredient:

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Study

View/Edit

# **FEE FOR SERVICE**



Providing Safe and Effective Pest  
Management Solutions for  
Specialty Crop Growers

IR-4 Headquarters  
Rutgers, The State University of New Jersey  
500 College Road East, Suite 201 W  
Princeton, NJ 08540  
732.932.9575  
fax: 609.514.2612  
ir4.rutgers.edu

Shanaz Bacchus  
Biopesticides & Pollution Prevention Division  
C/o Document Processing Desk  
Office of Pesticide Programs  
U. S. Environmental Protection Agency  
One Potomac Drive  
2777 S. Crystal Drive  
Arlington, VA 22202  
703-308-8097

December 1, 2009

Microbial Biopesticide  
IR-4 PRIA FEE EXEMPT

RE: Petition- Exemption from tolerance for *Aspergillus flavus* AF36 /Corn  
Company number 71693

Dear Shanaz:

The undersigned, Michael Braverman of the IR-4 project, submits this petition pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide product, requesting an exemption from tolerance for *Aspergillus flavus* AF36. Attached hereto, in triplicate and constituting a part of this petition, are the following:

- A. The name, chemical identity, and composition of the pesticide chemical. (If the pesticide chemical is an ingredient of an economic poison, the complete quantitative formula of the resulting economic poison should be submitted. The submission of this information does not restrict the application of any tolerance or exemption granted to the specific formula(s) submitted.)
- B. The amount, frequency, and time of application of the pesticide chemical.
- C. Full reports of investigations made with respect to the safety of the pesticide chemical.
- D. The results of tests on the amount of residue remaining, including a description of the analytical method used.
- E. Practicable methods for removing residue that exceeds any proposed tolerance.
- F. Proposed tolerances for the pesticide chemical if tolerances are proposed.
- G. Reasonable grounds in support of the petition.

A waiver of the petition fee is requested because this exemption from tolerance will be in the public interest. Furthermore, the Arizona Cotton Research and Protection Council is a grower based commodity group and that payment of the fee would work an unreasonable hardship on the organization.

Major funding for IR-4 is provided by Special Research Grants and Hatch Act Funds from USDA-CSREES,  
in cooperation with the State Agricultural Experiment Stations, and USDA-ARS.

Very truly yours,



Michael Braverman, Ph.D.  
Biopesticide Manager,  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201W  
Princeton, New Jersey 08540

**LIST OF VOLUMES INCLUDED IN THIS SUBMISSION**

- VOLUME 1 OF 3    Tolerance Petition Establishment of a Exemption  
from tolerance for Aspergillus flavus –AF36 in or on  
Corn.. Nov 25, 2009 19 pages.
- VOLUME 2 OF 3    Registration Volume-Administrative materials  
Dec 7, 2009 20 pages.
- VOLUME 3 OF 3    Product Performance Data Efficacy of AF36 in Corn . Dec 7,  
2009 233 pages.

## Request for Exemption from the Requirements of a Tolerance AF36 on Corn

### EPA BIOPESTICIDES AND POLLUTION PREVENTION DIVISION COMPANY NOTICE OF FILING FOR PESTICIDE PETITIONS PUBLISHED IN THE FEDERAL REGISTER (7/1/2006)

EPA has received a pesticide petition from [Interregional Research Project Number 4 (IR-4), Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540 on behalf of the Arizona Cotton Research and Protection Council], [3721 East Wier Avenue Phoenix, Arizona 85040-2933] proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.1206 to establish a tolerance exemption for the microbial pesticide [*Aspergillus flavus* AF36] in or on Corn.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, [Interregional Research Project Number 4 (IR-4), Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540 on behalf of the Arizona Cotton Research and Protection Council] has submitted the following summary of information, data, and arguments in support of the pesticide petition. This summary was prepared by [Interregional Research Project Number 4 (IR-4) Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540 on behalf of the Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933] and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

I. [Interregional Research Project Number 4 (IR-4), Rutgers University, 500 College Road East, Suite 201W, Princeton, NJ 08540 on behalf of the Arizona Cotton Research and Protection Council 3721 East Wier Avenue Phoenix, Arizona 85040-2933] Petition Summary

#### *A. Product name and Proposed Use Practices*

*Aspergillus flavus* AF36, a non-aflatoxin-producing strain of *A. flavus*, is proposed for application to corn to reduce the incidence of aflatoxin producing strains of *A. flavus* and thereby reduce aflatoxin contamination of corn. *Aspergillus flavus* AF36 which does not produce aflatoxin, competitively excludes aflatoxin producing *A. flavus* strains without increasing *A.*



*flavus* in the environment in the long term. Sterile wheat seed colonized with *Aspergillus flavus* AF36 is applied at 10 pounds of end-use product (total amount of active ingredient less than 0.01 lb/acre) per acre. The pesticide is currently being used in certain counties in California and the States of Arizona and Texas in cotton. The current submission proposes to establish an exemption from tolerance for residues of *A. flavus* AF36 on corn.

## B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* [The pesticide and corresponding residues are identified as *Aspergillus flavus* AF36. ]

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* [*Aspergillus flavus* AF36 is a naturally occurring fungus that was originally isolated from cottonseed produced in the Yuma Valley of Arizona. *Aspergillus flavus* AF36 has been shown to be naturally and consistently associated with corn grown in Texas. *A. flavus* is a widespread fungus. It is particularly well adapted to the hot regions of the southwest where it is widespread in the environment. The communities of *A. flavus* in the desert and in agricultural fields are naturally composed of both aflatoxin producing (toxigenic) and aflatoxin non-producing (atoxigenic) strains. The goal of applications is to increase the percent of the *Aspergillus flavus* community composed of the strain AF36 and to decrease the percent of *A. flavus* that produces aflatoxins on the crop and the field.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An exemption from the requirement of a tolerance for residues of the microbial pesticide *A. flavus* AF36 in/on corn is being proposed for corn. All lots of the active ingredient (*A. flavus* isolate AF36) and the formulated product are monitored as part of a rigorous quality control program. Starter cultures of *A. flavus* isolate AF36 used in the production of the end-use product are always screened for aflatoxin production using TLC and appropriate standards. Quality control standards are zero tolerance in the starter cultures and in the formulated product for aflatoxin production, and for *A. flavus* not identified as *A. flavus* isolate AF36. *A. flavus* AF36 has never been found to produce aflatoxin. Starter cultures of *A. flavus* AF36 as well as end-use products containing this active ingredient are also identified to isolate by vegetative compatibility analysis. Since AF36 is a naturally occurring fungus it will be present on corn regardless of treatment, therefore there is no need to distinguish or analyze between treated and non treated corn.

## C. Mammalian Toxicological Profile

An acute oral toxicity test was performed whereby a single oral dose of 5,000 milligrams/kilogram (mg/kg) per animal of *Aspergillus flavus* AF36 colonized wheat seed was administered by gavage to five male and five female Sprague Dawley rats. The oral LD<sub>50</sub> of *Aspergillus flavus* AF36 was determined to be greater than 5,000 mg/kg rat body weight. No

clinical signs were observed during the 14 day study and no abnormalities or adverse effects were observed in any of the rats upon necropsy.

An initial pulmonary rat study which resulted in lethality in a significant number of animals treated with either the live *Aspergillus flavus* AF36 in Tween 80 or heat killed *Aspergillus flavus* AF36 in Tween 80. Onset of symptoms was rapid after dosing with all deaths occurring by day four of the study. All rats surviving to day four of the study recovered and all rats sacrificed (as scheduled) on day 8 or day 15 of the study had totally eliminated viable *Aspergillus flavus* AF36 from the lungs, caecal contents, and faeces. There was no evidence of infectivity. The aetiology of deaths was unclear. It appeared that *Aspergillus flavus* AF36 prepared using Tween 80 caused a severe acute inflammatory response. Retrospective literature review and consultation with a toxicologist supported the theory that the responses were a result of a synergism with Tween 80 and/or of Tween 80 breakdown products formed during preparation of the spore suspension.

A second rat study was therefore undertaken. In the second study the conidia were both washed from the wheat and suspended in sterile physiological saline instead of Tween 80. Animals (2 male and 2 female for each treatment level) were dosed at 0,  $10^5$ ,  $10^6$ ,  $10^7$ , and  $10^8$  colony forming units per rat. There were no clinical signs in any of the treatment groups considered to be associated with the test substance. Rats were sacrificed at day 8 without treatment associated mortality. No abnormalities were observed in any of the animals at the macroscopic examination at termination.

Based on these two mammalian studies, it was concluded that *Aspergillus flavus* AF36 does not present either a toxicological or an infectious risk to mammals.

Data waivers were requested for the toxicology studies listed below on the following basis: (1) researchers and other workers have worked with *Aspergillus flavus* AF36 at the Southern Regional Research Center for over 10 years and in commercial fields (1996 to 1998) and in hand picked field plots (1989 to 1994) without report of any adverse health effects; (2) *Aspergillus flavus* AF36 is widely distributed in the environment and its occurrence is natural; and (3) the label will require applicators and other handlers to wear Personal Protective Equipment (PPE) such as waterproof gloves, a dust/mist filtering respirator with the appropriate NIOSH approval prefix N-95, P-95, or R-95, coveralls, long sleeved shirt and long pants, and shoes plus socks, and goggles, so exposure should not be a problem. Applications will involve aerial application by mixers/handlers who are licensed and trained to even handle restricted materials. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre. Applications of AF36 do not significantly impact the total amount of *Aspergillus flavus* in the soil or crop, but only change the proportion of the AF36 strain in relation to the overall soil or crop population. Since the product is applied as a granular formulation on wheat, exposure from drift is minimal.

1. Acute dermal toxicity. This study was waived based upon the lack of toxicity in animals dosed orally. While *Aspergillus flavus* has been reported to be a dermal sensitizer, this testing is not warranted, since the PPE required on the label will provide adequate protection from dermal exposure to workers and pesticide handlers.

2. Primary dermal irritation. This study was waived based upon the lack of toxicity in animals dosed orally. Aerial applications will be made by mixers/handlers and applicators, who are required to wear appropriate PPE, and are licensed and trained to even handle restricted materials. At the 10 lb/acre application rate of the formulated material, the total amount of active ingredient is less than 0.01 lb/acre. Applications of AF36 do not significantly impact the total amount of *Aspergillus flavus* in the soil or crop, but only change the proportion of the AF36 strain in relation to the overall population. Since the product is applied as a granular formulation on wheat, exposure from drift is minimal.

3 Primary eye irritation. This study was waived based upon the use of appropriate PPE, including goggles, and other factors listed above. Since the product is applied aerially as a granular formulation on wheat, exposure from drift is expected to be minimal.

4. Acute Intraperitoneal. This study was waived based upon the lack of toxicity in animals dosed orally and by intratracheal instillation. In addition, the factors listed above will mitigate exposure, which is expected to be minimal.

5. Genotoxicity, reproductive and developmental toxicity, subchronic toxicity and chronic toxicity testing were not performed, since no adverse effects were observed in the acute toxicology study Tier 1 studies. Tier II (885.3550), subchronic toxicology study (USEPA OPPTS 885.3600) and chronic feeding studies (guideline 152-50) are only required if triggered by adverse effects observed in Tier I studies.

#### D. Aggregate Exposure

##### 1. Dietary exposure.

i. *Food.* *Aspergillus flavus* AF36 is a naturally occurring organism, which does not produce aflatoxin and is thus safer than the aflatoxin-producing *A. flavus* isolates that produce aflatoxin. Proposed uses and application rates will not result in increases in the total population of *A. flavus* on the mature crop beyond naturally occurring background levels.

*Aspergillus flavus* AF36, has been shown to significantly reduce the levels of aflatoxin in corn at harvest without changing the quantity of *A. flavus* on the crop. Furthermore, the proposed use and application rate will not increase exposure of humans to *A. flavus* by dietary means. Applications of *Aspergillus flavus* AF36 do not increase the indigenous populations of *A. flavus* associated with the harvested crop. The applications merely alter the composition of the fungal community associated with the mature crop so that aflatoxin producing strains are far less frequent. The result is a much lower incidence of aflatoxins in the crop and in the environment associated with the developing and mature crop.

ii. *Drinking water* *Aspergillus flavus* AF36 is a naturally occurring organism that is already widespread in the environment and is not considered to be a risk to drinking water. Both

percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure of *A. flavus* through the drinking water. Applications of *Aspergillus flavus* AF36 do not increase the long-term populations of *A. flavus* in the environment, and thus are not expected to influence the relationship of *A. flavus* to water sources. Applications merely change the composition of the *A. flavus* community so that aflatoxins are less common in the environment.

2. *Non-dietary exposure.* The potential for non-occupational, non-dietary exposure to the general population is not expected to be significant and is not expected to present any risk of adverse health effects.]

#### E. Cumulative Exposure

There are no other registered products containing *Aspergillus flavus* AF36 or any other isolates (strains) of the microbial active ingredient. Data submitted show that the fungal metabolite of concern which is aflatoxin is not produced by *Aspergillus flavus* AF36. *Aspergillus flavus* AF36 has been shown to exclude aflatoxin producing fungi competitively from the developing crop and to reduce aflatoxin contamination of corn. Data show that the proposed use will not result in appreciable increases in the long-term population of *A. flavus* on the crop beyond naturally occurring levels. Furthermore, there is no expectation of cumulative effects with other pesticides.

#### F. Safety Determination

1. *U.S. population.* *Aspergillus flavus* AF36 is a naturally occurring organism. This isolate has low toxicity as demonstrated by the acute oral toxicity study in rats. *A. flavus* is ubiquitous throughout the hot desert valleys in Arizona. Studies have shown that treatment of cotton fields just prior to flowering with sterile wheat seed colonized by *Aspergillus flavus* AF36 at 10 lbs. per acre does not increase the long-term populations of *A. flavus* either on the crop at maturity or in the soil 1 year after application. Based on this information, the aggregate exposure to *A. flavus* over a lifetime should not change with application of *Aspergillus flavus* AF36, and exposure to both aflatoxin producing *A. flavus* strains and aflatoxin should decrease. This should be beneficial to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to *Aspergillus flavus* AF36.

2. *Infants and children.* Based on the lack of toxicity and natural occurrence, there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to *Aspergillus flavus* AF36. Exempting *Aspergillus flavus* AF36 from the requirement of a tolerance should pose no significant risk to humans or the environment.

#### G. Effects on the Immune and Endocrine Systems

*Aspergillus flavus* AF36 is a naturally occurring organism, which does not produce aflatoxin, and is thus safer than the *A. flavus* isolates that produce aflatoxin. To date there is no



evidence to suggest that *Aspergillus flavus* AF36 functions in a manner similar to any known hormone, or that it acts as an endocrine disrupter.

#### H. Existing Tolerances

The registrant is not aware of any existing tolerances or tolerance exemptions for *Aspergillus flavus* AF36, other than the tolerance exemption on cotton (40 CFR 180.1206)

#### I. Efficacy Data

The following information was presented for a tolerance exemption for AF36 on cotton. The information is relevant for corn because corn is grown in rotation with cotton. Therefore, the farms(soil) which would be treated with AF36 in corn are already able to be treated when those same fields are planted to cotton. This request is for a temporary exemption from the requirement of a tolerance for AF36 on corn, as part of the EUP contained herein. Existence of aflatoxins in the environment is a public health hazard, and as such data were submitted to demonstrate that proper use of *Aspergillus flavus* AF36 results in reductions in the average aflatoxin producing potential of fungi resident in treated areas and in reductions in the quantity of aflatoxins in crops. In field tests prior to 1996, the aflatoxin content of cottonseed was shown to be inversely related to the proportion of the *A. flavus* community on the crop composed of *Aspergillus flavus* AF36. Detailed analyses of the aflatoxin content of commercial fields from 1996 through 1998 confirmed that reduced aflatoxin levels were associated with displacement of aflatoxin producers by *Aspergillus flavus* AF36 from treated crops and that treatments were associated with up to 90% reductions in crop aflatoxin content. Efficacy of applications of *Aspergillus flavus* AF36 in displacing aflatoxin producers was demonstrated for fungal communities both on cottonseed from treated crops at harvest and in soils of treated fields one year after treatment. This included cotton crops treated in 1996 (112 acres treated), 1997 (463 acres treated), 1998 (499 acres), 1999 (10,488 acres), 2000 (16,725 acres) and 2001 (19,975 acres treated). Displacement of aflatoxin producers is indicated by the proportion of *A. flavus* communities composed of *Aspergillus flavus* strain AF36. In 1996 average incidence of AF36 on treated crops was 88.5% and in the soil one year after treatment, 85.2%. Incidences of AF36 on treated crops were 78% and 67% in 1997 and 1998, respectively, and in the soil one year after treatment incidences were 72% and 77%, respectively. Successful displacement was also observed as the acreage treated rapidly expanded from 1999 to 2001 with average incidences of AF36 on treated crops ranging from 57% in 1999 to 66% in 2001. Applications were particularly effective at displacing the high aflatoxin producing S strain of *A. flavus*. S strain isolates produce more aflatoxins than other *A. flavus* isolates and are prominent in soils of cotton producing areas of Arizona and South Texas. The use of *Aspergillus flavus* AF36 caused long-term reductions in the aflatoxin producing potential of fungal communities in agricultural fields. *Aspergillus flavus* AF36 retained atoxigenicity (failure to produce aflatoxins) upon repeated reisolation from treated fields one, two, or three years after treatment. Field averages for aflatoxin production by the displaced S strain isolates of *A. flavus* ranged from 7100-ppb aflatoxin to 22700 ppb aflatoxin. Thus, there was a long-term reduction in the potential of fungal communities to produce aflatoxins in treated areas.

There are preliminary data indicating that *A. flavus* AF36 is effective in corn as well. In a study, corn treated with AF36 reduced aflatoxin contamination by 80 to 95 %. The purpose of this temporary exemption from tolerance is to cover the use of *A. flavus* under an Experimental Use Permit so that additional efficacy data can be generated.

#### *J. International Tolerances*

There are no Codex maximum residue levels established for residues of *Aspergillus flavus* AF36. *Aspergillus flavus* AF36 containing products are presently not registered for pest control outside of the United States.



VOLUME 1 OF 3

Study Title

Tolerance Petition- Establishment of an Exemption from tolerance  
for Aspergillus flavus –AF36 in or on Corn

Author

Michael Braverman, Ph.D.  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201 W  
Princeton, New Jersey 08540

Submitted by

Michael Braverman, Ph.D.  
IR-4 Project, Rutgers University  
500 College Road East, Suite 201 W  
Princeton, New Jersey 08540

Study Completed On

November 25, 2009

Laboratory Project ID Number

IR-4 PR No. 0378B

Petition for Exemption from Tolerance  
**Aspergillus flavus- AF36**

**TABLE OF CONTENTS**

<b>Tab #</b>	<b>Section: description</b>
<b>A</b>	Section A: Name, chemical identity, and composition
<b>B</b>	Section B: Amount, frequency, and time of application of the pesticide chemical
<b>C</b>	Section C: Investigations made with respect to the safety of the active ingredient
<b>D</b>	Section D: Tests on the amount of residue remaining
<b>E</b>	Section E: Practicable methods for removing residue that exceeds any proposed tolerance
<b>F</b>	Section F: Proposed tolerances
<b>G</b>	Section G: Reasonable grounds in support of the petition

## Section A

### Name, chemical identity, and composition

**Please refer to the following volumes previously submitted to EPA .**

#### MRID Number and Title of Previously submitted Volumes

- 44626101 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 -Analysis of samples, Certification of Ingredient limits, :Amendment Number 2 to MRID No. 43763402 .
- 44713701 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 - Amended Manufacturing Process -- Amendment number 3.
- 44597001 Cotty, P. ; Antilla , L. (1998) Aspergillus flavus isolate AF 36 Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No. 2 to MRID 43763401
- 43763401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients.
- 43990001 Cotty, P. (1996) Aspergillus flavus isolate AF 36 Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients. Amendment No 1 to MRID 43763401.
- 43763402 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits and Physical and Chemical Properties.
- 43972401 Cotty, P. (1995) Aspergillus flavus isolate AF 36 Analysis of Samples, Certification of Ingredient Limits, Analytical Methods for Certified Limits Amendment No. 1 to MRID No. 43763404
- 46859501 Cotty, P. (2006) Volume 1 of 2 Microbial Product Analysis Data Requirements. Aspergillus flavus AF36.

## **Section B**

### **Amount, frequency, and time of application of the pesticide chemical**

Enclosed is the proposed label which describes the amount, frequency, and time of application of *Aspergillus flavus* AF36.

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized).....	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
<b>IF SWALLOWED:</b>	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
<b>IF INHALED:</b>	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>IF IN EYES:</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

**User Safety Recommendations:**

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

#### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

#### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



## Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

### CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

#### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

**User Safety Recommendations:**

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

#### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

~~Aerial Application: Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.~~

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

**User Safety Recommendations:**

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

#### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

#### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



# Aspergillus flavus AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
IF SWALLOWED:	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
IF INHALED:	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

## PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

### For other pesticide handlers under the scope of Worker Protection Standard:

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

### User Safety Recommendations:

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

## ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.



# *Aspergillus flavus* AF36

For displacing aflatoxin producing fungi

*Aspergillus flavus* AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to corn from the 7 leaf stage (V7) until silking, *Aspergillus flavus* AF36 competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and in so doing limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other ingredients: Wheat seeds (sterilized, colonized)	99.9992%
Total:	100%

\* Contains a minimum of 3,000 CFU/gram in the End Use Product

KEEP OUT OF REACH OF CHILDREN

## CAUTION

First Aid Statement	
<b>IF SWALLOWED:</b>	Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING:</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Get medical attention if irritation persists. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.
<b>IF INHALED:</b>	Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth to mouth if possible. Call a poison control center or doctor for further treatment advice.
<b>IF IN EYES:</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE ADDITIONAL PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration Number 71693  
EPA Establishment Number 71693-AZ-001

Arizona Cotton Research and Protection Council  
Phoenix, Arizona 85040

NET CONTENTS: 50 lbs, 1000-3000 lbs

### PRECAUTIONARY STATEMENTS HAZARD TO HUMAN AND DOMESTIC ANIMALS

**CAUTION:** Harmful if inhaled. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco, or using the toilet.

**For other pesticide handlers under the scope of Worker Protection Standard:**

Mixer/loaders, flaggers, markers, and applicators must wear long sleeve shirt, long pants, socks, shoes, gloves, goggles, and a dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or N-95, P-95, or R-95.

**User Safety Recommendations:**

User should: Remove clothing immediately if product gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

### ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where the surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment wash water. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Apply the pesticide only when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal. May be applied to irrigated corn fields. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in area during application. For any requirement specific to your State and Tribe, consult the agency responsible for pesticide regulation.

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), notification to workers, and restricted-entry interval. The requirements in this box apply to uses of this product that are within covered by the Worker Protection Standard

##### Re-Entry Statement:

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours, unless wearing appropriate PPE. Personal protective equipment required for early entry workers are: Coveralls, long sleeved shirt, long pants, waterproof gloves, shoes plus socks, goggles, dust/mist filtering respirator with MSHA/NIOSH approval number prefix N-95, P-95, or R-95 or TC-21C.

#### GENERAL USE PRECAUTIONS

Read all label directions before using. Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. *Aspergillus flavus* AF36 is for application to crops to displace aflatoxin-producing strains of *Aspergillus flavus*.

*Aspergillus flavus* AF36 is a living fungus growing on sterile wheat seed. The wheat seed serves as both a carrier and a nutrient source. After application and once the colonized seed is exposed to sufficient moisture (this may occur from irrigation, rain, dew, or high humidity), *Aspergillus flavus* AF36 will grow out and produce green spores on the seed. The fungus will appear on the wheat seed first as white fuzz and then as a green fuzz. These green spores will then be spread to the crop in the same manner that the aflatoxin producing fungi are spread.

##### Ground Application:

1. Apply *Aspergillus flavus* AF36 directly to the soil or over the plant canopy after last cultivation. Applications should be made from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE AF36 COLONIZED WHEAT SEEDS WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 and to minimize delivery of *Aspergillus flavus* AF36 to areas without crop.
3. Rain or irrigation within three days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre (per 13,000 linear feet based on 40 inch rows).

**Aerial Application:** Apply by air at the same rate as for ground application. Cultivation after application will diminish efficacy.

#### STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

**STORAGE:** Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F). Keep product dry.

**PESTICIDE DISPOSAL:** Purchase only the quantity of product needed and apply all product to the crop as specified in the directions. Return any unused material to manufacturer.

**CONTAINER DISPOSAL:** Plastic Bags (50 lbs.) - completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Containers- Completely empty container. Do not rinse container. Return empty containers to point of purchase. Containers returned to the distributor are not to be recycled for food/feed use, or for drinking water, bathing, or other human/animal uses.

#### WARRANTY STATEMENT

To the extent permitted by State Law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions given herewith.

## Section C

### Investigations made with respect to the safety of the active ingredient

Detailed information on the investigations made with respect to the safety of this product are provided in volume 4 of 4 of the **previous submission**.

Please refer to the following: MRID 47108902 Volume 4 of 4 Aspergillus flavus AF36 Health Effects Waiver Requests. 3-8-2007. 41 pages

Additional volumes previously submitted.

45798101 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat

45739101 - Aspergillus flavus isolate AF 36 -Acute Pulmonary Toxicity and Pathogenicity to the Rat -Interim Report.

45798102- Aspergillus flavus isolate AF 36 - Toxicity/ Pathogenicity to the Bob White Quail Avian Inhalation Test Tier 1.

43972403 Shelton, L. (1996) Acute Oral Toxicity in Rats:Aspergillus flavus isolate AF 36

43972402 Cotty, P. (1996) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity Amendment No. 1 to MRID 43763404

43763404 Cotty, P. (1995) Aspergillus flavus isolate AF 36 - Hypersensitivity Incidents With Microbial Pest Control Agents: Statement of Finding of No Hypersensitivity .

## **Section D**

### **Tests on the amount of residue remaining**

Residues analyses of the use of *Aspergillus flavus* AF36 is not appropriate because the active ingredient is a naturally-occurring organism for which an exemption from tolerance is being requested.

## **Section E**

### **Practicable methods for removing residue that exceeds any proposed tolerance**

As described in Section D, *Aspergillus flavus* AF36 is a naturally occurring organism. Since the petition is for an Exemption from a Tolerance, this section is not applicable.

## Section F

### **Proposed tolerances for the pesticide chemical *Aspergillus flavus* AF36 use in or on CORN**

This petition is for an Exemption from a Tolerance associated with the attached registration for use in or on Corn.

There is an existing exemption from tolerance 40CFR180.1206 for use on cotton. This petition amends the current tolerance exemption to add corn. The new tolerance exemption will now include both cotton and corn.

The petitioner, IR-4, on behalf of the state of Texas, requests the establishment of an exemption from the requirement of a tolerance. Specifically, it is proposed that:

*Aspergillus flavus AF36 is exempted from tolerance on Corn, Field.*

## **Section G**

### **Reasonable grounds in support of the petition**

The supporting documentation for the registration of *Aspergillus flavus* AF36 has demonstrated to have no potential for mammalian toxicity, there is clear potential to be efficacious and would be the only product for management of this important pest. Therefore, we feel that this exemption from tolerance will be in the public interest. There is an existing exemption from tolerance for AF36 in cotton. There are no known adverse effects from this use and there are no anticipated adverse effects from the expansion of the tolerance exemption to include corn.



